the Examiner requesting confirmation that the Amendment mailed November 19, 2002 was received by the Patent Office. Applicants' undersigned representative received a voicemail message from the Examiner on that same date specifically stating that the Office Action dated August 19, 2002 was **not** a final Action and, therefore, that Applicants' Amendment was placed on the Examiner's normal docket rather than the "after final" docket. Relying on this voicemail message from the Examiner, Applicants re-docketed the August 19 Office Action as "non-final." Applicants expected the next communication from the Patent Office to be either a Notice of Allowance or a further Office Action, not an Advisory Action. Applicants note that the Advisory Action was not mailed until February 11, 2003, even though Applicants' Amendment was mailed on November 19, 2002, *i.e.*, almost three months before the Advisory Action was mailed. Applicants further note that the Advisory Action was not received in the undersigned's office until February 18, 2003, *i.e.*, only one day prior to the statutory expiration date, thereby necessitating that Applicants file a Petition for a three month extension of time. Accordingly, reconsideration and withdrawal of the finality of the August 19 Office Action is respectfully requested.

In the Advisory Action, the Examiner indicated that the claims remain rejected under 35 USC §112 as nonenabled. Applicants respectfully maintain that the claimed invention is enabled. As noted previously, the Declaration of John Francis Martin, M.D. Under 37 CFR 1.132 shows that nucleic acid encoding a VEGF receptor agonist was successfully delivered and expressed in targeted blood vessel cells. Applicants assert that an application for patent is not required to show that a claimed method of treatment of a disease condition results in a cure of that disease condition, or even that clinical efficacy is achieved. The Federal Circuit has made it clear that the showing for therapeutic utility that is sufficient to satisfy the patent laws is not to be confused or equated with the showing required by the Food & Drug Administration for drugs, medical devices, and procedures. *Scott v. Finney*, 32 USPQ2d 1115 (Fed. Cir. 1994). Accordingly, Applicants respectfully assert that the subject specification enables the claimed nucleic acid-mediated treatment methods.

In regard to the Examiner's assertion that the rabbit animal model is not predictive for humans, Applicants respectfully maintain that the subject specification enables the claimed method for the treatment of mammals, including pigs and humans. It is well established in patent law that studies in humans are not required for claims where there is an animal model that is accepted in the

art. Applicants respectfully assert that for studies directed to treatment of blood vessels in mammals, the rabbit animal model is, and has been, accepted in the art and has been used extensively in studies reported in the scientific literature. The Strauss *et al.* (*Int. J. Radiation Oncology Biol. Phys.*, 2002, Vol. 54, No. 2) and Farb *et al.* (*Circulation*, 2001, Vol. 103) references were submitted to show that the rabbit is a suitable animal model and is still being used in studies for testing suitability of procedures in humans. If the rabbit model was not a valid model for procedures in humans, Applicants respectfully assert that clinical researchers would not use it for their studies and it is unlikely that studies using rabbits would continue to be published in the scientific literature. The fact that the rabbit model has been used in the past and continues to be used in current scientific studies is evidence that the rabbit was, and remains, a valid model for other mammals, including humans.

In regard to the Examiner's assertion that the Strauss *et al.* and Farb *et al.* references are of no significance because the references were published after the filing date of the application, Applicants' note that post-filing date publications are proper where they offered to show the state of the art on the filing date of an application. *Gould v. Quigg*, 3 USPQ2d 1302, 1305 (Fed. Cir. 1987). The cited references were not offered to supplement the disclosure in the subject application; rather, they were cited as evidence confirming the validity and usefulness of the rabbit model in the art. Applicants respectfully assert that as of the filing date of the subject application, the rabbit model was an accepted animal model for methods of treating intimal hyperplasia in humans and other mammals. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 USC §112.

In view of the foregoing remarks, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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